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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,502	09/18/2001	Diana Downs	960296.97559	9804

27114 7590 10/18/2004

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EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,502

Applicant(s)

DOWNS ET AL.

Examiner

Patricia A. Duffy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8-10-04.
- 2a) ☒ This action is **FINAL**: 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-10 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

The amendment filed 8-10-04 has been entered into the record. Claims 2-6 and 11-14 have been cancelled. Claim 15 is withdrawn from consideration. Claims 1 and 7-10 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claim 15 drawn to an invention nonelected without apparent traverse in responsive paper filed July 7, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

The rejection of claims 1, 2, 4 and 7 under 35 U.S.C. 102(b) as being anticipated by Portnoy et al (Journal of Biological Chemistry, 274(21):15041-15045, 1999) is withdrawn in view of the amendment to the claims to recite "eubacterial cell".

The rejection of claims 1, 2, 5 and 7 rejected under 35 U.S.C. 102(b) as being anticipated by Kelner et al (Journal of Biological Chemistry, 275(1):580-584, 2000) is withdrawn in view of the amendment to the claims to recite "eubacterial cell".

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The rejection of claims 1, 2, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Ben-Amor et al (Plant Cell and Environment, 22(12):1579-1586, 1999) is withdrawn in view of the amendment to the claims to recite "eubacterial cell".

Rejections Maintained

Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record for claims 1-8 in the Office action mailed 12-22-03.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the claims are not drawn to the YggX gene. As previously set forth, the recitation of "YggX" does not convey a common structure or function. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Structural features that could distinguish compounds in the "YggX" genus from others in the protein class are missing from the disclosure and the claims. Further, as previously set forth the written description is limited to methods that reduce superoxide damage to an eubacterial cell comprising vector-based *over-expression* of the *endogenous YggX gene* from said cell, wherein said overexpression renders the cells more resistant to superoxide damage.

The rejection is maintained.

Claims 9 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record for claims 9-14 in the Office action mailed 12-22-03.

Applicants argue that specification adequately describe and describe the use of the homologs of YggX protein and Applicants have included the subject matter of claim 8, describing an amino acid sequence motif into claim 9. This is not persuasive, claim 9 is an independent claim and does not recite a sequence identifier as it relates to the homolog. Further, as previously set forth recitation of "YggX" does not convey a common structure or function. The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Structural features that could distinguish compounds in the "YggX" genus from others in the protein class are missing from the disclosure and the claims.

The rejection is maintained.

Priority

With respect to the art rejections and the amended claims, Applicants argue that they are entitled to the priority date of the provisional documents. This is not persuasive because the provisional documents lack conception by way of written description for SEQ ID NO:1, lack written description and enablement for the presented claims for reasons previously made of record and maintained herein. Should Applicants wish to dispute this issue, they should point to the provisional document by page and line number where written description of SEQ ID NO:1 and the limitation of wherein there is no increased superoxide dismutase activity in the cells is found. The figures do not provide conception of SEQ ID NO:1, because SEQ ID NO:1 does not correspond to the particular motif presented in the Figures and therefore SEQ ID NO:1 has no written description in the provisional document as filed.

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Claims 1, 7 and 8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gralnick et al (Abstracts of the General meeting of the American Society for Microbiology, 100p441, May 21-25, 2000 is maintained for reasons made of record for claims 1, 2, 3, 7 and 8 in the Office action mailed 12-22-03.

Applicants' arguments with respect to priority to the provisional document were not persuasive for the reasons set forth directly above. Applicants indicated that a declaration was concurrently filed, but the declaration is not found to be of record in the electronic file. A second copy of the declaration should be submitted to complete the record. In any event, a declaration allegedly attesting to the identity of the authors J.A. Gralnick and D.M. Downs as being the same as the Applicants, cannot overcome a rejection under 102(b) as set forth supra.

Claims 1 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Pianzzola et al (Journal of Bacteriology 178(23):6736-6742, 1996 is maintained for reasons made of record for claims 1, 2, 3 and 7 in the Office action mailed 12-22-03.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the increased level of YggX is NOT associated with increased levels of an activity that eliminates superoxides. This is not persuasive, the specification teaches that there was "no increase in superoxide dismutase activity". This activity is not equivalent to the alleged "increased levels of an activity that eliminates superoxide". Superoxide dismutase is a specific enzyme that performs a particular catalysis. There exist other proteins that protect against superoxide (i.e. see Kelner et al of record) that are not the enzyme superoxide dismutase. Applicants are trying to extend a specific observation for superoxide dismutase, a particular enzyme, to all other proteins that function the same, the claims are not so limited and the specification fails to support such this interpretation. The claims are specifically drawn to "superoxide dismutase" and not

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all other proteins that have an activity to eliminate superoxides (i.e. scavenger proteins having non-catalytic activity and not related to superoxide dismutase. Therefore, suppressors of anti-oxidant activity and complement the specific loss of superoxide dismutase are not by definition enzymes, nor are they particularly superoxide dismutase. Kelner et al teach that the level of protection of these suppressors of anti-oxidant activity is comparable with superoxide dismutase. Therefore, mere complementation does not necessarily portend the isolation of the enzyme superoxide dismutase. Pianzzola et al teach that the corresponding rob protein in *Dulfovibrio vulgaris* encodes a putative rubredoxin oxidoreductase. Further, the endogenous levels of superoxide dismutase in the cells are not increased in the transformed bacterium because they are functionally deleted. Further, Pianzzola et al admit the gene as not being related to any known superoxide dismutase proteins (see page 6738, column 2, last sentence). Pianzzola et al teach that the function of rbo is unknown and several possibilities, aside from superoxide dismutase activity, are suggested by Pianzzola et al and include the possibility that rbo prevents superoxide generation or that reduces superoxide-oxidized clusters. (page 6741, column 1, second, third and fourth full paragraphs). Pianzzola et al conclude that rbo appears to be a new way to fight oxidative stress. There is no evidence of record that rbo is in fact a superoxide dismutase enzyme. Pianzzola et al do not teach that rbo is definitively and in fact a superoxide dismutase, but present a multitude of options. Since, there is no evidence of record that the expressed rbo protein is in fact a superoxide dismutase and in view of the teaching of Pianzzola et al that it is dissimilar to any superoxide dismutase gene sequences in the databases, Applicants arguments are not persuasive. In view of the lack of structure for YggX recited in the claims and in view that the rbo gene product functions the same, it meets the limitation of YggX protein. The recitation of YggX in the claim does not patentably distinguish the methods from other methods using differently named proteins that have the same functional effect.

New Rejections Based on Amendment

Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1, 7 and 8, the claims are confusing because they do not make it clear that the vector-based expression is in a eubacterial cell.

The term "increased" in claims 1, 7 and 8 is a relative term that renders the claim indefinite. The term "increased" is not defined by the claim, because it does not define what the increase is relative to. The claims do not provide a standard for ascertaining the requisite degree and relative partner and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention because the basis for comparison as it relates to an "increase" is not defined.

Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are now drawn to "wherein there is no increased superoxide dismutase activity in the cells" and points to [0058] for support for this limitation. [0058] Supports this concept as it applies to the specific over-expressed "YggX" and "YggX*" mutant specifically disclosed. The specification does not support conception of this property of the cell as it relates to the claimed genus homologs. There is written description of this property in association with homologs as now claimed.

Status of Claims

Claims 1 and 7-10 stand rejected. Claim 15 is withdrawn from consideration.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy
Patricia A. Duffy

Primary Examiner

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